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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,703	05/01/2001	Mark W. Kroll	A01P1028	6988

7590 09/08/2003

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EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	7

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,703	KROLL, MARK W.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/22/03 (Request for Reconsideration)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

1. The Applicant's arguments filed 7/22/03 have been fully considered and are convincing. The rejections of record are withdrawn and a new rejection is established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claims 1, 3-7, 16-18, 25-27, 29 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by Kramm (US 5766225).

Kramm discloses a system and method to sense cardiac signals and electrically stimulate the ventricles.

As to claims 1, 7, 8, 13, 14, 16, 17, 18, 20, 23-26, 29 and 30, capture of cardiac tissue is determined by sensing signals/ voltage differential/ time delay, both inherent and evoked, within an established time interval (abstract; col. 2 @ 39-45; col. 3 @ 14-15; col. 3 @ 44 - col. 4 @ 2; col. 4 @ 48-52).

Kramm incorporates by reference Williams (US 4932407) to teach leads (col. 3 @ 4-10).

Willaims teaches an endocardial defibrillation system using tip and ring biventricular electrodes that synchronously stimulate and sense cardiac tissue.

As to claims 1, synchronous biventricular stimulation is delivered between right and left ventricular electrodes (figures 1, 2, 5A, 5C; col. 2 @ 45-68; col. 3 @ 21-41; col. 3 @ 63 – col. 4 @ 7; col. 5 @ 1-35 and col. 56-64; co. 5 @ 65 – col. 6 @ 26; especially col. 6 @ 5-6 and 18-21).

As to claim 3, polarities are selected to control the waveform (col. 4 @ 41-44).

As to claims 4 and 5, the pulse is biphasic or monophasic (col. 6 @ 54-59).

As to claim 7, bipolar sensing in the right chamber verifies capture (col. 2 @ 63-68).

Williams incorporates by reference Smits (US 4641656) to teach polarity control (col. 6 @ 14-16).

As to claim 6, Smits teaches delivering a positive pulse to one electrode/ group of electrodes and a negative pulse to the second electrode/ group of electrodes (col. 2 @ 51-57).

3. Claims 1, 2, 7-9, 11-13, 18, 22, 23 and 25-30 are rejected under 35 U.S.C. 102(e) as anticipated by Salo et al. (US 6278894). Salo et al. disclose a multi-site stimulator and impedance sensor using right atrial, right ventricular and coronary sinus electrodes (abstract; figure 1; col. 1 @ 6-10; col. 2 @ 49-62; col. 3 @ 32-65; col. 4 @ 21-32; col. 4 @ 66 – col. 5 @ 3; col. 5 @ 23-27, 43-53 and 54-65).

Claim Rejections - 35 USC § 103

4. Claims 14-17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al. (US 6278894). As discussed in paragraph 3 of this action, Salo et al. disclose the claimed invention except for defining the stimulation sensing configurations of A) stimulating with first and second left electrodes and sensing with first and second right electrodes, and B) sensing with left atrial and right ventricular electrodes.

Salo et al. teach cardiac diagnosis and therapy using multiple stimulation and sensing configurations for the purpose of maximizing the understanding of cardiac dynamics to enable

selection of simulation configurations that optimize cardiac output (col. 3 @ 32-65). This statement provides a clear suggestion that electrodes included in the stimulation pair and in the sensing pair can be modified to optimize the understanding of the cardiac tissue dynamics, hence enabling stimulation that improves cardiac output. The variation in the stimulation and sensing configurations is read to include stimulating with first and second left electrodes and sensing with first and second right electrodes, and sensing with left atrial and right ventricular electrodes. The determination of the most appropriate stimulation and sensing configurations by routine experimentation would, therefore, be prima facie obvious to one having ordinary still in the cardiac stimulation and monitoring art.

5. Claims 3, 6, 10 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al. (US 6278894) in view of Weinberg et al. (US 5476485). As discussed in paragraph 3 of this action, Salo et al. discloses the claimed invention except for varying the polarity of the electrodes during stimulation and sensing.

Weinberg et al. teach cardiac stimulation and sensing using control of the polarity of the electrodes during stimulation and sensing for the purpose of providing directional control for the stimulation and sensing. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used control of the polarity of stimulation and sensing electrodes in the Salo et al. system in order to provide additional control of the stimulation and sensing so the cardiac dynamics can be more precisely understood and by optimal stimulation, the cardiac output can be optimized (col. 1 @ 7-13; col. 4 @ 20 – col. 5 @ 25; col. 5 @ 31-40).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner 8-30-03
Art Unit 3762

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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